

**DISCUSSION DOCUMENT ONLY**  
**DOES NOT REPRESENT DEPARTMENT POLICY/REGULATION**  
**DRAFT as of November 4, 2003**

**CHAPTER 20**

**DEPURATION**

The section number for an existing regulation is noted in brackets [20.01].  
The electronic copy is available at [www.maine.gov/dmr/](http://www.maine.gov/dmr/).

Title section:

See grammatical changes throughout. Highlighted text indicates primary changes since last version.

Chapter 20 has been updated for compliance with the MO and HACCP rules per federal regulations. Several sections in Chapter 20 are duplicates of sections that have been consolidated in Chapters 15, 16 or 18. For example, Chapter 16 contains existing section 20.09 Physical Plant, section 20.10 Water Quality rules on process water, plus equipment handling, cleaning, plumbing, sewage and labeling, etc.

20.01 [15.02, 20.29] Compliance

20.02 [20.01, 20.24] Depuration

20.03 [20.24] Receiving Critical Control Point - Critical Limits

20.04 [20.16, 20.20] Processing Critical Control Point - Critical Limits

20.05 Shellstock Storage Critical Control Point - Critical Limits Citations corrected.

20.06 Depuration Process Water

20.07 [20.24] Harvest of Shellfish for Depuration

20.08 [20.25] Transportation and Delivery of Shellfish for Depuration

Tags are no longer sold in numerical order. They are sold in batches of 20 and the truck driver records the seal number and tag numbers.

20.09 [20.26] State Seals

State seals no longer say depuration on them. Ask Marine Patrol if this section is still necessary or do we have enough controls without this.

20.10 Plant Operating Manual

20.11 Process Verification

20.12 Conditional Protocol Verification

20.13 [20.23, 20.24] Records

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**CHAPTER 20**

**DEPURATION**

20.01 Compliance

Each depuration processor must comply with the requirements specified in Chapter 15, Chapter 16, and Chapter 18 that are appropriate to the plant and the shellfish being processed.

20.02 Depuration

- A. The holder of a depuration certificate issued pursuant to 12 M.R.S.A. §6856 may cleanse shellfish harvested from approved, conditionally approved, restricted or conditionally restricted areas, using a physical plant and processing methods which are approved by the Commissioner and which comply with the requirements set forth in this chapter.
- B. The holder of a depuration certificate may purchase, receive or harvest shellstock from areas classified as approved, conditionally approved, restricted or conditionally restricted and submit such shellstock to an approved depuration process. The depuration processor may pack, sell, ship or transport the depurated shellstock. A depuration processor shall have a facility, including a means of refrigerated storage of shellfish, such as a walk – in cooler.

20.03 Receiving Critical Control Point - Critical Limits.

The depuration processor may receive and depurate only shellstock, which is:

- A. Obtained from a licensed harvester who has:
  - 1. Harvested the shellstock from an approved or conditionally approved area in the open status as indicated by the tag; and
  - 2. Identified the shellstock with a tag on each container or transaction record on each bulk shipment; or
- B. Originates from a certified dealer who has identified the shellstock with a tag on each container; or
- C. Obtained from an authorized representative in accordance with Chapter 20.07 who has:
  - 1. Harvested or supervised the harvest of shellstock from a restricted or conditionally restricted area in the open status: and
  - 2. Identified the shellstock by transaction records, which include the harvest area, the authorized representative's name, the licensed harvester name(s), harvester license number(s), the harvest date, and the amount of shellstock shipped in each lot.

20.04 Processing Critical Control Point - Critical Limits

The depuration processor must:

- A. Depurate all lots for a minimum of 44 hours;
- B. Monitor the water treatment system **to assure** that it is operating at design specifications.
- C. Monitor that the critical limits established during **process verification for compliance with the requirements of Chapter 20.11 and 20.12.**

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20.05 Shellstock Storage Critical Control Point - Critical Limits

The depuration processor must ensure that:

- A. If onshore wet storage is practiced, water quality meets the requirements outlined in Chapter 15.32, 15.33 and 15.34; and
- B. Once placed under temperature control and until sale to the processor or final consumer, the shellstock:
  - 1. Is placed in a storage area or conveyance with mechanical refrigeration and maintained at 45 °Fahrenheit (7.2 °Centigrade) or less; and
  - 2. Is not permitted to remain without ice for more than 2 hours at points of transfer such as loading docks.
    - (a) Methods other than ice or mechanical refrigeration must be approved by the Department prior to use.

20.06 Depuration Process Water

- A. Water from a prohibited growing area must not be used for source water.
- B. The depuration processor must:
  - 1. Continuously treat process water with a disinfection system that is approved by the Department and does not leave any unacceptable residue in the shellstock; and
  - 2. Verify that the disinfection system produces process seawater with no detectable coliform organisms, as measured using an NSSP approved method, in the tank influent according to the following sampling protocols:
    - (a) If the source water is from an approved growing area, approved well, or other approved source, then the tank influent produced by each disinfection unit must be evaluated **i.e., tested**, once per process batch;
    - (b) If the source water is from a restricted growing area, then:
      - (i) A study meeting the requirements of Chapter 15.33(J) is required; and
      - (ii) The tank influent produced by each disinfection unit must be **tested** daily.

20.07 Harvest of Shellfish for Depuration

- A. Each depuration plant certificate holder must submit an application to the Department on an annual basis the names **and addresses** of individuals who the certificate holder intends to use as authorized representatives for the depuration plant in depuration harvesting operations. **The Commissioner may refuse to authorize any person that he determines to be unsuitable to serve as an authorized representative, taking into account, among other things, whether that person has a record of having committed marine resource law violations.**
- B. The authorized representative must supervise all members of the depuration harvesting crew and keep accurate records **in accordance with Chapter 20.07(C) below**.
- C. The authorized representative must record the names of all depuration harvest crewmembers and their current, valid, shellfish harvester's license number, during each day's operation. These records must be available for inspection by department personnel at all times.

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- D. The authorized representative must maintain daily records of the quantity of shellfish harvested by each member of the harvest crew and the area where the shellfish were harvested. These records must be available for inspection by department personnel at all times.
- E. The depuration plant authorized representative must call the appropriate Maine State Police communications center to notify the local marine patrol officer of the area to be harvested at least 24 hours prior to actual harvesting.
- F. Harvesting in moderately contaminated areas for depuration purposes may be undertaken only during daylight hours, except during the months of November, December, January, and February when harvesting may be permitted until 8:00 P.M. in areas approved by the Department marine patrol officer. In the event that a marine patrol officer approves an area for nighttime harvesting, the authorized representative must notify the officer at least 12 hours in advance of the planned nighttime harvest. The Department will determine the number of areas approved for nighttime harvesting.
- G. During depuration harvesting activities, all harvest crew diggers must remain in the same area, close enough for immediate supervision of all diggers at all times by the authorized representative.
- H. Each member of a depuration harvesting crew must hold, and possess on his person, a current, valid commercial shellfish license, at all times during depuration harvest activities,.

**20.08 Transportation and Delivery of Shellfish for Depuration**

All shellfish harvested from depuration areas must be placed into an approved vehicle and the vehicle must be sealed immediately. Unless otherwise authorized by Marine Patrol, all shellfish harvested must be transported directly to the depuration plant immediately after digging operations are completed.

- A. The vehicles must be sealed with state seals, issued by depuration plant managers. The authorized representative or the vehicle driver must record the seal number(s) on the daily harvest record.
- B. The authorized representative must maintain harvest records as required under Chapter 20.07(D), and must record the number of the seal on the vehicle and the time shellfish were placed on the vehicle. The plant manager must also maintain records of shellfish lots, listing each lot by seal number and listing the time the lot arrived at the plant and the time the seal was removed from the vehicle at the plant.
- C. The vehicle used must conform to the requirements set forth in Chapter 16.23.

**20.09 State Seals**

The Department will issue state seals for depuration harvesting purposes only to a depuration plant manager. It shall be unlawful for any person, other than a depuration plant manager or an authorized representative, to possess these seals. Unused seals must be submitted to the Department of Marine Resources upon cancellation or suspension of a shellfish certificate, or revocation or suspension of a certification to depurate.

**20.10 Plant Operating Manual**

- A. The depuration processor must prepare a written Depuration Plant Operations Manual (DPOM) meeting the minimum requirements described below. The DPOM must be updated as needed. A copy of the DPOM must be kept in a location readily accessible to the trained personnel responsible for the depuration activity. The minimum requirements for a DPOM must include:

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1. An introduction, including;
  - (a) The status of document (to create, revise or update DPOM);
  - (b) Ownership and principal(s) involved with operation of facility;
  - (c) The address and phone number of owner(s) and principal(s); and
  - (d) A summary of proposed use of the depuration facility including statement of objectives of the operation of the plant, species to be processed, proposed periods of facility operation, proposed sources of shellfish, including potential harvest areas, and maximum capacity of plant.
2. A description of facility, including:
  - (a) Site plan drawing(s);
  - (b) Facility layout, including detailed schematic of the entire depuration system;
  - (c) A schematic drawing of the depuration process;
  - (d) A product flow diagram showing product movement through facility;
  - (e) A statement that construction materials and fabrication will meet the requirements of Chapter 16.12; and
  - (f) A schematic of the seawater delivery, treatment and distribution system(s).
3. Design specifications of the Depuration Unit including;
  - (a) Diagram of the depuration tank(s), including tank dimensions and construction details, influent and effluent locations, operating water level, and typical container configuration;
  - (b) A description of the process water system, including type of system (flow through or recirculating), pretreatment and filtration systems, disinfection system, and hydraulic schematic;
  - (c) Shellfish containers construction and material meeting the requirements of Chapter 16.08 and 16.14; and
  - (d) A list of all equipment, including washing, culling, and packing equipment, material handling equipment, and cleaning and sanitizing equipment.
4. The laboratory to be utilized for microbial analyses (in house, government agency, private commercial);
5. Depuration process monitoring, including;
  - (a) Sampling protocols, including frequency of sampling, number of samples, sampling locations, and methodology for process water analyzing, incoming shellstock and depurated shellstock;
  - (b) Monitoring equipment maintenance and calibration procedures and copies of activity log forms that will be used for data entry;
  - (c) Process water monitoring protocol for physical and chemical parameters; and

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- (d) Data analysis and evaluation.
- 6. Standard Operating Procedures for:
  - (a) Receiving and holding;
  - (b) Washing, culling, and placement of undepurated product in process tanks;
  - (c) Depuration unit operation;
  - (d) Monitoring of depuration unit operation;
  - (e) Removal of depurated product from process tanks;
  - (f) Storage parameters and procedures;
  - (g) Labeling/tagging procedures;
  - (h) Plant cleaning and sanitation;
  - (i) Data analysis; and
  - (j) Recall procedures.
- 7. Copies of proposed forms to be used for record keeping and a list of the categories of information that will be recorded, including:
  - (a) Shipping and receiving records;
  - (b) Plant Operation Log, including provisions for recording the values for chemical and physical parameters;
  - (c) Maintenance and Sanitation Log(s); and
  - (d) Laboratory records.

20.11 Process Verification

- A. The depuration processor must continuously perform process verification according to the following protocol:
  - 1. Following completion of a minimum of 44 hours of depuration, at least one end-product sample from each lot of shellstock to be depurated in the depuration unit must be collected and assayed.
  - 2. The depuration performance indices, defined as the geometric mean and 90<sup>th</sup> percentile of fecal coliform (FC) from assay data of the most recent ten (10) consecutive harvest lots for each species depurated and for each restricted harvest area used, must be determined daily, or as soon as results become available.
  - 3. The depuration performance indices, with the following Critical Limits for the Indices of Depuration Plant Performance table below, must be compared daily, or as soon as results become available:

Limits for Verification of Depuration Plant Performance  
Fecal Coliform per 100 grams

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Species	Geometric Mean	90 <sup>th</sup> Percentile
Soft Clams ( <i>Mya arenaria</i> )	50	130
Hard Clams ( <i>Mercenaria mercenaria</i> )	20	70
Oysters	20	70
Manilla Clams	20	70
Mussels	20	70

4. If the depuration performance indices for a specific species from a specific growing area are less than or equal to the above Critical Limits for the Indices of Depuration Plant Performance, then the process is considered verified for that species from that growing area.

20.12 Conditional Protocol Verification

- A. If the depuration performance indices for a specific growing area fail to meet the Critical Limits for the Indices of Depuration Plant Performance, or if a new restricted growing area is used as a source of shellfish for depuration, or if a new depuration process has generated less than 10 process batches of data, the process is considered to be unverified and the depuration processor shall adhere to the following conditional protocols:
  1. The depuration processor shall collect and assay at least one zero hour and three end-product samples from each harvest lot;
  2. Environmental parameters, including process water temperature, salinity, dissolved oxygen, and turbidity and other operational conditions that may inhibit the physiological process, must be identified. These condition(s), once identified and quantified, become critical control points (CCP) for specific species in the specific plant and the hazard analysis and HACCP plan must be revised accordingly.
  3. Shellstock which are processed during this conditional protocol must meet the following release criteria before they may be released to market:
    - (a) The geometric mean (from three samples) of soft shelled clams does not exceed 110 and no single sample exceeds 170; or
    - (b) The geometric mean (from three samples) of other clam species, mussels, or oysters does not exceed 45 and no single sample exceeds 100.
  4. If the harvest lot fails to meet the release criteria, the depuration processor may choose to subject the product to additional depuration processing, after which the shellfish may be resampled for compliance with the release criteria. Otherwise, the disposition of the shellfish shall be as follows:
    - (a) The Department, in consultation with the depuration processor, may order the destruction of the shellfish;
    - (b) The Department, in consultation with the depuration processor, may allow non-food use of the shellfish; or
    - (c) The Department, in consultation with the depuration processor, may allow the shellfish to be relayed in accordance with Chapters 21 and 22.
  5. When depuration units with multiple tanks are used it is necessary to determine whether the individual tanks are similar.
    - (a) Tanks are considered similar if the difference between physical tank dimensions and process water flow rate is less than 10%.

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- (b) If the tanks are not similar, then the process verification protocols contained in Chapter 20.11 must be employed for each tank.
- 6. All microbiological assays of end-point samples must be analyzed by a laboratory which has been evaluated and approved pursuant to the requirements in the NSSP Guide for the Control of Molluscan Shellfish, Revision 1999, Chapter III, using an NSSP approved method.
- 7. Sample size must consist of a pool of at least 12 shellfish selected at random from each designated container (more than 12 individuals may be required in the case of smaller shellfish).
- 8. Samples must be collected at locations within the depuration unit that are considered to be most compromised with respect to the shellfish activity, based on the sampling plan contained in the DPOM.

20.13 Records

- A. Each depuration certificate holder must maintain the following records, in addition to those described in Chapters 15.25, 15.29, 15.30:
  - 1. Daily dig records as required by Chapter 20.07(D);
  - 2. Daily sales records as required by regulations promulgated under 12 M.R.S.A., §6856, and numbers of bushels received, sold and held in process tanks.
  - 3. All quality assurance records required must be maintained for at least two years.
- B. Records must be maintained at the plant and be available for inspection by department personnel.